

REMARKS

Claims 1-12 are pending in the instant application. The claims are subject to a Restriction Requirement which has been made final. Claims 6-8 have been cancelled as being directed to the non-elected Group II from the Restriction requirement, without prejudice to pursuing the subject matter of those claims in a subsequently filed application. Applicants have also cancelled Claims 1, 3-5 and 11-12. New Claims 13-18 have been added. Applicants respectfully request reconsideration of the application in light of these remarks.

Applicants respectfully thank Examiner Bland for telephonically discussing the examination of the elected species compound (the compound of formula II) with Applicants' Attorney Muthard. In light of comments made by the Examiner, Applicants have amended Claims 2, 9 and 10 and added new Claims 13-18 to be directed the elected species and the two other compound species (the compounds of the formulae III and IV) and their solvates and/or salts.

The Examiner notes that no English translation of the priority document PCT/JP03/09393 was submitted.

The Examiner notes that the specification as filed (English translation) includes a Brief Description of Drawings, but no drawings were included with the translation. Applicants respectfully contend that omission of the drawings from the English translation was an unintentional error. Applicants note that the drawings were included in the copy of the International Application that was communicated to the USPTO by the International Bureau. Applicants have attached to this Response an English translation copy of the Drawings (labeled "New Sheet" in the margin). Applicants have also included a Verification of Translation of that English translation. Since the English language copy of the Drawings is merely a translation of the Japanese language version of the same drawings that were submitted by the International Bureau at the time of the US National Phase filing, Applicants respectfully contend that the introduction of these English language drawings does not introduce new matter to the Application as filed.

The Examiner has rejected Claims 1, 2 and 9-12 under 35 U.S.C. 112, first paragraph. The Examiner suggests that the specification does not enable claims of the scope that also includes crystalline solvates of the compound of formula I. Applicants note that the Claims 1 and 11-12 have been cancelled without prejudice to filing an application directed to that subject matter. Applicants also note that Claim 2 has been rewritten as amended Claim 2 and

new Claims 13-14. Current Claims 2 and 13-14 are directed to specific free base, salt and solvates of the compounds of formulae II, III and IV respectively. Applicants note that all of the crystalline forms now being claimed in Claims 2 and 13-14 are specifically disclosed in the specification as originally filed, and methods of preparing those crystalline forms along with physical characteristics of those forms are also described. Applicants therefore respectfully contend that specific, detailed enablement of those crystalline forms of compounds II, III and IV are provided in the specification and that the Examiner's rejection of Claims 1, 2 and 9-12 is now moot and should be withdrawn.

The Examiner has rejected Claims 9-12 under 35 U.S.C. 102(b) as being anticipated by Kojiri et al. (JP 10-245390, English translation). The Examiner suggests that the Kojiri reference describes the compound of the formula II and describes the injectable solution of that compound. The Examiner further suggests that an injectable solution of the compound made from an amorphous form would be the same as a solution made from a crystalline form of the same compound. Applicants note that Claims 9-10 as amended and new Claims 14-15 and 17-18 are directed to compositions and agents that comprise the compounds/salts and solvates in solid crystalline forms. As such, the compositions and anti-tumor agents being claimed are not anticipated by the disclosure by Kojiri et al. of injectable solutions. Applicants therefore respectfully contend that the rejection of Claims 9-12 under 35 U.S.C. 102(b) is now moot and should be withdrawn.

The Examiner has rejected Claims 1 and 2 under 35 U.S.C. 103(a) as being unpatentable over the Kojiri et al. JP 10-245390 reference. The Examiner suggests that the Kojiri et al. reference teaches that the compounds disclosed therein (including the compound of the formula II) may be "purified by methods known in the field of organic chemistry, for example by . . . recrystallization" (emphasis added). Applicants respectfully note that the Kojiri et al. reference does not specifically suggest recrystallizing already purified amorphous forms of the compounds disclosed therein. Applicants note that there is no suggestion in the Kojiri et al. reference that the compounds disclosed therein may be beneficially improved (other than made more pure) upon the recrystallization of the free base or particular salts. The instant application clearly shows the claimed crystalline forms of the free bases and salts of the compounds of the formulae II, III and IV all exhibit a variety of improved physical characteristics that are unexpected and not suggested by the disclosure in Kojiri et al. reference to merely purify by recrystallization. Applicants particularly note the data presented in Figures 1-4 and Tables 1 and 2. In light of the lack of teaching, motivation and suggestion that recrystallization would

particularly benefit the compounds of formulae II, III and IV and the unexpected beneficial properties of the instantly claimed crystalline forms, Applicants respectfully contend that the Examiner's rejection of Claims 1 and 2 under 35 U.S.C. 103(a) is untenable and should be withdrawn.

Applicants respectfully contend that the Examiner's rejections have been addressed by the above amendments and remarks, and that Claims 2, 9-10 and 13-18 are allowable and an early Notice of Allowance is earnestly solicited. If a telephonic communication with Applicants' representative will aid in the advancement of the prosecution of this application, please telephone the representative indicated below.

Respectfully submitted,

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Attachments: English translation copy of drawings
Verification of translation

VERIFICATION OF TRANSLATION

I, Isao YOKOYAMA, a Japanese Patent Attorney registered No. 11604 having my business office at Banyu Pharmaceutical Co., Ltd., Kitanomaru Square, 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo 102-8667, Japan, do hereby certify:

1. That I am familiar with the Japanese language and the English language; and
2. That, to the best of my knowledge and belief, the attached document represents a true and correct English language translation of Figures of PCT international Application No. PCT/JP2004/010741 (our case BY0018YP), which was filed with the Japan Receiving Office on July 21, 2004.

Signed at Tokyo, Japan, this 5th day of June, 2008

A handwritten signature in cursive script, reading "Isao Yokoyama", is positioned above a horizontal line.

Isao YOKOYAMA